



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2023-0020]

Laboratory Recommendations for Syphilis Testing in the United States

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comment on the proposed Laboratory Recommendations for Syphilis Testing in the United States. The proposed recommendations for syphilis testing include laboratory-based tests, point-of-care tests, processing of samples, and reporting of test results. The recommendations are intended to aid laboratorians and clinicians in the diagnosis of syphilis. These proposed recommendations are intended for use by clinical laboratory directors, laboratory staff, clinicians, and disease control personnel who must choose

among the multiple available testing methods, establish standard operating procedures for collecting and processing specimens, interpret test results for laboratory reporting, and counsel and treat patients in the United States.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2023-0020 by either of the methods listed below.

Do not submit comments by email. CDC does not accept comments by email.

- Federal eRulemaking Portal:
<http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Division of STD Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop US12-2, Atlanta, GA 30329, Attn: Docket No. CDC-2023-0020.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background

documents or comments received, go to

<http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: John R. Papp, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop U12-3, Atlanta, GA 30329; Telephone: 404-639-8000; Email: jwp6@cdc.gov.

SUPPLEMENTARY INFORMATION: CDC's proposed Laboratory Recommendations for Syphilis Testing in the United States is available under the Supporting and Related Materials tab in the docket for this notice, Docket No. CDC-2023-0020, on <http://www.regulations.gov>.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. In addition, CDC invites comments specifically on the following questions proposed in this Notice:

- Based on the evidence presented in the full recommendations document (see the Supporting and Related Materials tab in the docket), does the evidence support the proposed Laboratory Recommendations for Syphilis Testing in the United States? If not, please state the reason why and, if available, provide additional evidence for

consideration.

- Are CDC's proposed Laboratory Recommendations for Syphilis Testing in the United States (see Supporting and Related Materials) clearly written? If not, what changes do you propose to make them clearer?
- If implemented as currently drafted, do you believe the proposed recommendations would result in improved laboratory testing for syphilis in the United States? If not, please provide an explanation and supporting data or evidence.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure.

Comments will be posted on <https://www.regulations.gov>.

Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. **Do not submit comments by email.**

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Background

Syphilis is a notifiable disease, with over 130,000 cases in the United States reported to the CDC in 2020 (CDC, 2020) and over 6 million new cases reported worldwide (World Health Organization, 2018). Syphilis is caused by *Treponema pallidum* subspecies *pallidum*. The United States is currently experiencing a syphilis epidemic, with sustained increases in primary and secondary syphilis. In 2000, 5,979 cases were reported; in 2020 the figure rose to 133,945 cases, a 2,140% increase (CDC, 2001, 2020). The epidemic is characterized by health disparities, particularly among sexual and gender minority populations, intersections with the HIV and substance use epidemics, and increased morbidity and mortality attributable to congenital syphilis infections (CDC, 2020). Laboratories play a critical role in the public health response to the syphilis epidemic. The responsibility of the laboratory is to test specimens and report results in a timely manner, allowing clinicians to efficiently make diagnoses and institute patient management protocols. Public health reporting by laboratories also allows local health departments and CDC to conduct surveillance and monitoring of disease trends. CDC used current evidence to draft the proposed Laboratory Recommendations for Syphilis Testing in the United States to improve laboratory testing for

syphilis and aid laboratorians and clinicians in the
diagnosis of the disease.

Dated: March 31, 2023.

Tiffany Brown,

Acting Executive Secretary,

Centers for Disease Control and Prevention.

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